

Nenunkumbi/Edahiyedo (“We Are Here Now”): A Mult-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth

Principal Investigator

Elizabeth Rink PhD, MSW
Associate Professor
Department of Health and Health Development
Montana State University
Bozeman, Montana
Email: elizabeth.rink@montana.edu

Supported by:

The National Institute of Minority Health and Health Disparities
National Institute of Health
Grant Number: R01 MD012701-02

Study Intervention Provided by:

Nenunkumbi/Edahiyedo (“We Are Here Now”) is an equitable collaborative community-academic partnership grounded in trust, respect, mutual understanding and a commitment to improving the lives of young people and their families on the Fort Peck Indian Reservation.

Nenunkumbi/Edahiyedo (“We Are Here Now”) is implemented by: Fort Peck Community College, the Fort Peck Tribes Language and Cultural Program, the Fort Peck Tribal Health Department, the school districts of Frazer, Wolf Point, Poplar, Brockton and Culbertson and Montana State University.

SECTION 1: STUDY SUMMARY

American Indian (AI) communities in the United States (US) are disproportionately affected by sexual and reproductive health disparities, compared to other populations, placing current and future generations of AI societies in jeopardy. Our study, “Nen ŪnkUmbi/EdaHiYedo (N/E - “We are Here Now”)", utilizes a culturally tailored ecological intervention in which the prevention of sexual-risk behaviors among AI youth that lead to STIs, HIV, HCV, and teen pregnancy are addressed. N/E takes place on the Fort Peck Reservation in northeastern Montana. N/E is a community-based participatory research sexual and reproductive health (SRH) intervention, constructed on Ecological Systems Theory. Based on Fort Peck tribal members' desire to implement a holistic SRH intervention for the tribes' youth, N/E includes: 1) A school-based SRH curriculum called Native Stand, designed to address individual-level factors that lead to risky behaviors; 2) a family-level curriculum called Native Voices, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the community-level that pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a systems-level strategy to activate a multi-sectoral network of local youth servicing organizations to coordinate SRH services. The overarching aim of this proposal is to refine and tailor the components of N/E and evaluate its efficacy. N/E is a 5-year study involving 456 15- to 18-year-old AI youth and their parent/legal guardian.

SECTION 2: STUDY PROTOCOL

2.1 Study Team Roster. N/E's tribal community and academic study team combine Indigenous expertise in traditional knowledge, contemporary reservation culture, and local tribal resources and skills with Westernized research experience in SRH interventions among Indigenous populations and qualitative and quantitative research methodologies. The study team members are listed below.

- **Elizabeth Rink**, Ph.D., MSW, at Montana State University (MSU) is the principal investigator (PI) for N/E. Dr. Rink will be responsible for the overall research and fiscal administration, implementation, and evaluation of N/E.
Email: elizabeth.rink@montana.edu
- **Paula FireMoon** (Sioux), M.A., is N/E's Fort Peck-based Project Director. Ms. FireMoon will oversee community participation, including implementation of N/E, and coordination of N/E's research activities with tribal schools, health care facilities, and other youth-servicing agencies on the Fort Peck Reservation.
Email: PFiremoon@fpcc.edu.
- **Ramey Growing Thunder** (Sioux/Navajo), M.Ed., is director of the Fort Peck Tribes' Language and Culture Department. Mrs. Growing Thunder will lead the implementation of N/E's cultural mentoring program.
Email: rgrowingthunder@gmail.com.
- **Adriann Ricker** (Assiniboine), MPH, CHES, is associate director of the Fort Peck Tribes' Health Promotion and Disease Prevention Program. Ms. Ricker will increase coordination among, and access to, SRH services for AI youth in schools, health care facilities, and youth-servicing agencies at Fort Peck.
Email: adricker@gmail.com.
- **Community Advisory Board** (CAB) that includes five Assiniboine and Sioux tribal members. CAB members are: Ingrid FireMoon – Email: IFiremoon@fortpecktribes.net, Bruce Bauer – Email: bwbauer@yahoo.com, eOlivia Johnson – Email: ojohnson@brockton.k12.mt.us; Martel Reum – Email: MReum@fpcc.edu; and Alexandria Herrald - Email: alexandria.herrald26@gmail.com.
- **Julie Baldwin** (Cherokee), Ph.D., director of The Center for Health Equity Research at Northern Arizona University, with over 20 years of research expertise in the design, implementation, and evaluation of HIV and substance abuse prevention interventions for AI youth is the study's Co-Investigator and senior research mentor to Dr. Rink.

*Nenunkumbi/Edahiyedo (“We Are Here Now”):
A Mult-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth*

Study Protocol and Statistical Analysis Plan

Email: Julie.Baldwin@nau.edu.

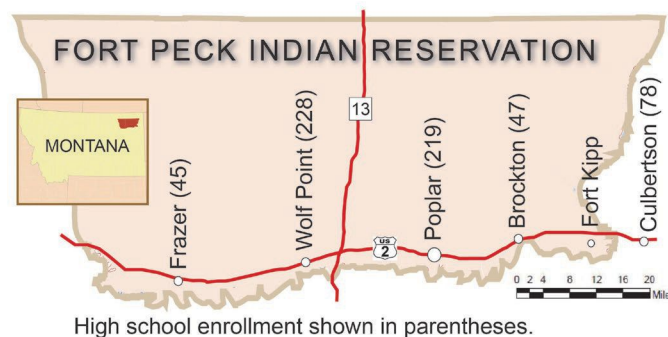
- **Mike Anastario**, Ph.D., is Co-Investigator and statistician for the study.
Email: mike.anastario@gmail.com.
- **Rachel Hallum-Montes**, Ph.D., an independent contractor who has worked on a variety of national teen pregnancy–prevention studies with the CDC will consult on the assessment of the coordination and implementation of SRH services for AI youth.
Email: rhallum.montes@gmail.com.
- **Genevieve Cox**, Ph.D., N/E’s MSU-based research program manager.
Email: genevieve.cox@montana.edu.

2.2 Study Sites. N/E will be implemented on the Fort Peck Reservation in Northeastern Montana. Fort Peck is located in a Northern Plains frontier environment and spans 2.1 million acres. It borders the 47½ parallel to the north (just south of the border with Canada), with Big Muddy Creek to the east, the Missouri River to the south, and Big Porcupine Creek to the west. Approximately 8,000 enrolled tribal members, predominately from the Assiniboiné and Sioux Nations, live on the reservation. The Assiniboiné and Sioux are descendants of the Nakoda, Nakota, Nakona, Lakota, and Dakota Nations. The Assiniboiné comprise Wadopana (Canoe Paddlers Who Live on the Prairie) and Hudashana (Red Bottom) bands, and the Sioux comprise Sisseton/Wahpetons, the Yanktonais, and the Teton Hunkpapa bands. N/E will be implemented in the communities of Frazer, Wolf Point, Poplar, Brockton, and Culbertson. These 5 communities have public high schools that serve AI students. Frazer, Wolf Point, Poplar, and Brockton are on the reservation, and Culbertson is a border town on the east end of the reservation that AI youth from the reservation community of Fort Kipp attend (See Figure 1 for map of reservation and high schools).

Collaborating entities in N/E are:

- Montana State University, 318 Herrick Hall, Bozeman, MT. 59715, phone: 406.994.3833, Fax: 406.994.2013
- Fort Peck Community College, PO Box 398 Poplar, MT. 59255, phone: (406) 768-6300, Fax: 768.6301.
- The Fort Peck Tribes Language and Cultural Department, 603 Court Avenue, PO Box 1027, Poplar, MT. 59255, phone: 406.768.3520, Fax: 406.768.3531.
- The Fort Peck Tribal Health Department, 107 H Street East, PO Box 1027, Poplar, MT. 59255, Phone: 406. 653.1191, Fax: 406. 768.5780.
- Frazer Public School, 325 6th Street, Frazer, MT. 59225, Phone: 406.695.2241, Fax: 406. 695.2243.
- Wolf Point School District, 213 6th Ave. South, Wolf Point, MT. 59201, Phone: 406.653.2361, Fax: 406. 653.3405.
- Poplar School District, 400 4th Avenue West, Poplar, MT. 59255, Phone: 406.768.6600, Fax: 406.768.6800.
- Brockton School District, 215 North 5th Street, Brockton, MT. 59213, Phone: 406.768.3311, Fax: 406. 786.3377.
- Culbertson School, 423 1st Avenue West, P.O. Box 459, Culbertson, MT. 59218, Phone: 406.787.6241, Fax: 406.787.6244.

Figure 1. Study sites on or near the Fort Peck Reservation.



2.3 RESEARCH DESIGN OVERVIEW

2.3.1 Study Title. Nenunkumbi/Edahiyedo (“We Are Here Now”): A Multi-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth

2.3.2 Study Aims.

- **AIM 1** begins with a year of formative work to refine and tailor the components of N/E. Our community advisory board and the Fort Peck-based and MSU-based research team will design culturally appropriate adaptations for N/E’s 4 levels.
- **AIM 2** tests the efficacy of N/E using a cluster-randomized stepped-wedge design (SWD), in which the 5 high schools that Fort Peck youth attend are randomized into the intervention 1 at a time. N/E’s primary outcome is increased condom use during sexual intercourse. Secondary outcomes are delayed onset of sexual intercourse, number of sex partners, frequency of sexual intercourse, pregnancy history, consistent use of birth control during sexual intercourse, and whether alcohol and/or other drugs are used during sexual intercourse. Tertiary outcomes are increased parent/legal guardian-child communication about SRH topics, increased understanding of cultural values related to traditional AI beliefs regarding SRH, and increased use of SRH services. Quantitative data collection includes: student surveys at baseline, 3, 9 and 12 months; parent/legal guardian surveys at baseline, 9 and 12 months. Qualitative data collection includes SRH service provider discussion groups at baseline and thereafter once a year over the 5-year study, with logs to track coordination and implementation at baseline and 3, 6, 9 and 12 months.
- **AIM 3** will evaluate the fidelity and acceptability of N/E with focus groups, activity logs, and staff meeting notes and staff field notes.

Our **long-term goal** is to produce a toolkit, including curriculum manuals, an SRH cultural mentoring program, and specific systems-level actions suitable for replication in other tribal communities. The **public health impact** is the prevention of STIs, HIV, HCV, and teen pregnancies in AI youth resulting in reduced sexual and reproductive health disparities and improved health in AI families and communities.

2.3.3 Design. N/E is a community-based participatory research (CBPR) multi-level, multi-component sexual and reproductive health (SRH) intervention, constructed on Ecological Systems Theory. N/E is based on Fort Peck tribal members’ desire to implement a holistic SRH intervention for AI youth. N/E includes: 1) A school-based SRH curriculum called *Native Stand*, designed to address **individual-level** factors that lead to sexual risk behaviors; 2) a **family-level** curriculum called *Native Voices*, tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the **community level** that pairs AI youth with adults and elders to discuss traditional AI beliefs and practices about SRH; and 4) a mobilizing strategy to activate a multi-sectoral network of youth-servicing organizations at the **systems level** in Fort Peck to coordinate SRH services for AI youth. The overarching aim of this study is to refine, tailor, and finalize the components of N/E and evaluate its efficacy. We will use a cluster-randomized stepped-wedge design (SWD), in which 5 schools that AI youth from Fort Peck attend are the clusters to be randomized into the intervention 1 at a time, with all schools eventually being randomized to the intervention. The 5 schools are located in separate communities, mitigating the potential for cross-contamination. N/E is a 5-year study involving 456 15- to 18-year-old AI youth.

2.3.4 Intervention Design. N/E is a 5-year CBPR ecological intervention for 456 15- to 18-year-old AI youth living on the Fort Peck Reservation. *Nen ŨnkUmbi/EdaHiYedo* (“We Are Here Now”) derives from the Assiniboine (*Nen ŨnkUmbi*) and Sioux (*EdaHiYedo*) names for their traditional coming-of-age ceremonies, when, at the age of 15 and over, young tribal members are believed to be ready for integrated education and training on sex, what it means to be a man or a woman, relationships, having children, and being a parent. N/E is guided by a 5-member CAB. The primary institutional partners responsible for the implementation of N/E are

*Nenunkumbi/Edahiyedo (“We Are Here Now”):
A Multi-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth*

Study Protocol and Statistical Analysis Plan

Fort Peck Community College (FPCC), the Fort Peck Tribes Language and Culture Program, the Fort Peck Tribal Health Department (Epi Team)¹, and MSU.

N/E will be implemented simultaneously over the 9-month school year (Table 1). Components include: 1) **Individual Level.** *Native Stand* is a school-based, 27-module STI-, HIV-, and teen pregnancy-prevention curriculum, originally developed for rural white youth and adapted in 2008 as a stand-alone SRH curriculum for AI youth. For *N/E*, an adaptation of *Native Stand* will be implemented in the study's 5 high schools to educate AI youth on sexual risk behavior prevention strategies. The tailoring of *Native Stand* will reduce its 27 modules to 18 modules and will include specific community-relevant traditional and contemporary cultural lesson plans. *Native Stand* will be integrated into each of the 5 schools' established curriculum and will be delivered by the *N/E* School Coordinator in a classroom setting as part of the students' regular class schedule. 2) **Family Level.** *Native Voices* is a video-based HIV/STI-prevention intervention designed for AI youth to address condom use, negotiation skills, group discussion, and role playing. *Native Voices* will be adapted from 1 module into 4 modules to involve parents/legal guardians, as recommended by the CDC. Our adaptation of *Native Voices* involves students with one of their parents/legal guardians to promote parent/legal guardian/youth discussions about preventing STIs, HIV, HCV, and teen pregnancy. The *N/E* School Coordinator will present *Native Voices* to groups of students and their parents/legal guardians at the study's high schools for 2 hours in the evening. 3) **Community Level.** The third level of *N/E* is a cultural mentoring component that pairs AI youth with older adults and elders to discuss traditional AI beliefs and practices about reproductive health. The mentoring program is based on Assiniboine and Sioux traditional knowledge and the National Mentoring Partnership standards for mentoring. The mentoring program was designed specifically for Fort Peck youth by the Fort Peck Tribes' Language and Culture Department and has been in existence for 5 years. *N/E* integrates this cultural mentoring program into *N/E*'s overall framework with an emphasis on addressing traditional topics related to SRH, such as overall information on cultural beliefs, values, and ceremonies, and more specific information on cultural beliefs and values regarding sex, having children, parenting, and relationships. Our cultural mentoring program will include older male and female tribal members who will be paired with the youth by gender and tribal affiliation. AI youth will meet one-on-one with their mentors each month and also monthly in mentor-mentee small groups. Depending on the purpose of the cultural mentoring sessions, the sessions will take place at either the study's high schools, the Fort Peck Language and Culture Department's main office in Poplar, community centers on the reservation, or at the Buffalo Ranch. Ramey Growing Thunder will oversee the implementation of the cultural mentoring program. 4) **Systems Level.** The fourth level of *N/E* mobilizes the existing Epi Team to enhance the coordination and implementation of SRH services at Fort Peck. The members of the Epi Team will utilize the recommendations in the CDC's *Contraceptive and Reproductive Health Services for Teens: Evidence-based Clinical Best Practices Guide* to enhance the coordination and implementation of SRH services for AI youth. This enhancement process will take place during the Epi Team's monthly meetings at the Fort Peck Tribal Headquarters in Poplar by developing a coordination and monitoring plan that can be tracked over time to address the barriers, facilitators, and solutions to increase access to SRH services for AI youth at Fort Peck. Dr. Rink, Ms. FireMoon, Ms. Ricker and Dr. Cox will attend the Epi Team's monthly meetings to work in partnership to implement *N/E*'s systems-level component.

¹ Fort Peck Tribal Epidemiology Team (Epi Team), which is a local committee that has been in existence for 15 years to monitor diseases on the reservation and the health status of tribal members. The Epi Team is comprised of the Fort Peck Tribal Health Department; the Indian Health Service (Poplar Service Unit and Wolf Point Service Unit); the Roosevelt County Health Department; school nurses from the Fort Peck Health Promotion and Disease Prevention Program; the high schools of Frazer, Wolf Point, Poplar, Brockton, and Culbertson; and the Fort Peck Tribal Executive Board.

Table 1. Overview of *N/E*'s 9-month multi-level, multi-component intervention plan.

INDIVIDUAL	FAMILY	COMMUNITY	SYSTEMS
Native Stand (NS): 18-session school-based curriculum delivered twice a month over 9 months in <i>N/E</i> 's 5 participating schools. NS will be integrated into the schools' existing class schedules.	Native Voices (NV): 4 sessions delivered once every other month to students and parents/legal guardians after school hours at <i>N/E</i> 's 5 participating schools.	Cultural Mentoring Program (CMP): 9 mentoring sessions delivered twice a month over 9 months that include one group activity with CMP mentors and mentees and one 1:1 meeting. CMP activities will take place at varying locations on the Reservation depending on the activity.	SRH Services: Monthly meetings over 12 months with Epi Team at the Fort Peck Tribes Headquarters offices in Poplar, Montana.
NS 1: Introduction to an overview of <i>N/E</i> and Native Stand	NV 1: Introduction to an overview of <i>N/E</i> and Native Voices	CMP 1: Assiniboine/Sioux kinship networks and concepts of family and genealogy	Epi Team meetings will take place monthly over 9 months to enhance coordination and implementation of SRH services for AI youth.
NS 2: Culture & Tradition – Part 1		CMP 2: Traditional male/female roles and cultural beliefs about healthy relationships	
NS 3: Culture & Tradition – Part 2			
NS 4: Healthy Relationships – Part 1			
NS 5: Healthy Relationships – Part 2	NV 2: Talking with youth about topics related to sex	CMP 3: Cultural beliefs about sex and how to make decisions about sex that integrate cultural values	
NS 6: Reproductive Health – Part 1		CMP 4: Cultural beliefs about parenting and the role of family	
NS 7: Reproductive Health – Part 2			
NS 8: Pregnancy & Parenting			
NS 9: Preventing Pregnancy	NV 3: Prevention of STIs, HIV/AIDS, and HCV	CMP 5: The role of ceremony in traditional Assiniboine/Sioux culture	
NS 10: Condoms & Birth Control		CMP 6: The role of sweat lodges in AI spirituality	
NS 11: Sexually Transmitted Diseases			
NS 12: HIV/AIDS & HCV			
NS 13: Drugs, Alcohol, & Sex	NV 4: Strategies for fostering healthy relationships in your child's intimate relationships	CMP 7: Honoring ceremonies in the lives of young men and women	
NS 14: Mental Health & Sex		CMP 8: Understanding the sacredness of the land	
NS 15: Negotiation & Refusal Skills			
NS 16: Decision-Making			
NS 17: Effective Communication		CMP 9: Buffalo Harvest	
NS 18: Putting It All Together			

2.3.5 Trial Design. Our selection of an SWD to evaluate *N/E* is consistent with tribal members' desires that all 15- to 18-year-old AI youth receive the intervention. The SWD is a cluster-randomized trial, which involves random and sequential crossover of clusters from control to intervention until all clusters are exposed to the intervention.⁽²⁵⁻²⁹⁾ The first observation period corresponds to a baseline measurement observation, in which none of the clusters have been randomized to *N/E*. Clusters are randomized to *N/E* at subsequent steps until all clusters have completed treatment. ***Following randomization of the schools to the intervention, there will be three waves of implementation: Wave 1 (1 school in 2019), Wave 2 (2 schools in 2019-2020), and Wave 3 (2 schools in 2020-2021).*** The 5 schools on the Fort Peck Reservation will be the clusters that are randomized to *N/E*. *N/E* will take approximately 40 weeks, or 3 quarters, to implement. The first observation period (Q4 of Year 2) provides baseline measurements for all respondents drawn from every cluster. The cluster is then surveyed at 3, 9, and 12 months for the students in the cluster once they have begun participation in the intervention, and at 9 and 12 months for the parents/legal guardians in the cluster once they have begun participation in the intervention. Following completion of the intervention across all clusters, we will conduct the quantitative analysis. The SWD allows us to control for the effect of time and ensure that the full AI population of schools at Fort Peck receives *N/E*. The systems-level component of *N/E* will be implemented reservation-wide rather than school-wide during Years 2 to 4 of *N/E* as the SWD is rolled out. The systems-level component will be measured and analyzed qualitatively.

2.3.6 Trial Timeline. The timeline for *N/E* is: **Year 1**—Refine, tailor, and finalize the components of *N/E* with the CAB by reviewing our current quantitative and qualitative data from Fort Peck and by talking with elders and community stakeholders. We will have monthly team meetings and quarterly CAB meetings. When necessary, we will meet with CAB members individually. We will also recruit, hire, and train staff in *Native Stand* and *Native Voices*; identify the cultural mentors; purchase all necessary materials and supplies; finalize research protocols and IRB approvals. **Years 2, 3, and 4**—Collect baseline data; Implement *N/E*; conduct

quantitative and qualitative data collection; conduct ongoing fidelity and acceptability data collection; and continue monthly team meetings and quarterly CAB meetings. *Year 5*—Finish data collection; conduct data analysis; work with CAB on interpretation of data analysis; develop sustainability plan; develop intervention toolkit; and disseminate results to scientific, professional, and Fort Peck communities.

2.3.7 Sample Size and Population. N/E's sample size is 456 AI male and female youth ages 15 to 18 years old. The population of AI youth 15 to 18 year old attending the five schools participating in the study is approximately 617.

2.3.8 Study Background and Rationale. Comprehensive national surveillance data on SRH among AIs is difficult to assess due to the underrepresentation of AIs in national surveys. The data on AI SRH in the United States that are available demonstrate that AIs are disproportionately affected by adverse conditions attributable to SRH, compared to other populations. AI youth report earlier onset of sexual intercourse than other adolescent populations in the U.S. The teen birth rate among AIs is 2 to 3 times higher than that among Caucasians. In addition, the rates of pre-term birth and low birth weight are much higher in AIs compared to Caucasians. STIs are up to 4.6 times higher for AI males and females compared to Caucasians, with young AI males having the highest chlamydia rates of any racial- and age-specific population in the U.S. As a result, AI females have higher rates of miscarriages and ectopic pregnancies than Caucasian females and are at risk for infertility. For AI males, STIs can lead to urethritis, epididymitis, and prostate cancer, which is higher in AI men than all other racial and ethnic males in the U.S. In addition, the costly and burdensome health consequences of AI youths' high STI rates include infection with HIV and HCV. The incidence of HIV in AI males and females is 30% higher than in Caucasian males and females, and in recent years AIs are the only racial and ethnic group in which the incidence of HIV continues to rise. Furthermore, of all population subgroups in the U.S., the incidence of HCV is highest in AIs. At present no extant multi-level, multi-component intervention has been shown to be efficacious in addressing SRH among AI youth. The majority of AI interventions appearing in the peer-reviewed literature instead focus on alcohol and substance use reduction. Thus, a critical need exists to address the SRH disparities among AI youth, which place current and future generations of AI societies in jeopardy.

The literature related to SRH among AI youth identifies poverty, isolation, alcohol and other drug use, physical and sexual victimization, and lack of comprehensive and coordinated SRH education and clinical services as factors that influence unintended pregnancies and STIs. Evidence also suggests that ambivalence toward sex, social pressures, depression, anxiety, and experiences of historical trauma and loss influences sexual risk behavior among AIs. Mistrust of research and researchers continues in AI communities due to a legacy of neglect and betrayal by the U.S. government and by researchers from outside their communities. This mistrust impedes the cooperation between tribal communities and academics to design, implement, and evaluate effective interventions to address SRH disparities among AI youth.

The complex factors that influence sexual risk behaviors among AI youth warrant novel AI community-specific interventions. Previous research with AI youth on SRH has lacked an ecological design and implementation, and it has neither addressed nor leveraged the interconnectedness of the individual, family, community, and larger systems in preventing STIs, HIV, HCV, and teen pregnancy. Furthermore, CBPR, which has become an established methodological framework for partnering with AI communities to conduct research, has been sparsely applied to understanding and addressing Indigenous SRH. CBPR has the potential to facilitate the implementation and evaluation of an ecological intervention in AI communities, particularly given its amenability to multi-sectoral and multi-level stakeholder involvement in the research process.

SECTION 3: ANALYSIS PLAN

3.1.1 Power analysis. Sample size requirements were calculated taking into account a unique design effect for the SWD,² such that $N_{sw} = N_u \times DE_{sw}$ (where N_u is the total number of students needed to detect the treatment effect with a power of 80% and a significance level of 0.05, uncorrected for cluster and repeated measurements). The design effect was calculated as:

$DE_{sw} = \frac{1+\rho(ktn+bn-1)}{1+\rho(\frac{1}{2}ktn+bn-1)} \times \frac{3(1-\rho)}{2t(k-\frac{1}{k})}$, where k is the number of steps, n is the expected number of students per cluster, b is the number of baseline measurements, t is the number of measurements after each step, and ρ is the intra-class correlation coefficient, estimated to be 0.016 based on findings reported by Kaufman et al.³ With an α of 0.05, power of 0.8, $N_u = 292$, $DE_{sw} = 1.3273$, and the expectation of 15% attrition during the study, a sample size of 456 will allow the detection of a 0.14 increase in the proportion of condom use relative to the frequency of sexual intercourse from baseline to the 12-month observation period hypothesized under Aim 2.

3.1.2 Missing data. Attrition is likely to covary with truancy, suggesting a missing data mechanism that is not missing at random (NMAR). To address this, a dropout variable D_i will be developed for each individual across the 4 observation periods, where $D_i=k$ for dropout between the $(k-1)^{th}$ and k^{th} occasion. A model of the probability of dropout, where

$\log\left\{\frac{\Pr(D_i=k)}{\Pr(D_i>k)} \middle| \frac{D_i \geq k, Y_{i1}, \dots, Y_{ik}}{D_i > k, Y_{i1}, \dots, Y_{ik}}\right\} = \theta_1 + \theta_2 Y_{ik-1} + \theta_3 Y_{ik}$, presumes that $\theta_3 \neq 0$ for the NMAR mechanism. Missing data will be examined using multiple imputation, where missing values are replaced by a set of m plausible values using a propensity scoring sequence to generate a single estimate of the parameters of interest.⁴ Observations will first be grouped on the basis of propensity score similarity, then individuals with missing values will be randomly matched to those with observed values, and finally missing values will be randomly selected with replacement from the random sample of observed values. This sequence will be repeated sequentially starting at the 3-month follow-up observation through the 12-month follow-up observation, and the entire propensity scoring and time imputation sequence(s) will be repeated at minimum across ≥ 5 datasets (m) to estimate $\bar{\beta} = \frac{1}{m} \sum_{k=1}^m \hat{\beta}^{(k)}$. Sensitivity analyses will also be used to assess the robustness of primary results attributable to missing data by examining imputed and nonimputed data.

3.1.3 Dose. The treatment dose is the number of intervention components delivered to the individual student, accounting for individual students' attendance and participation. This will be tracked using the fidelity log, staff field notes, and the CAB meeting. A count, nominal, or weighted percentage will be used to represent dose pending analysis of the dose frequency distribution.

3.1.4 Baseline data analysis. Baseline data will first be analyzed to determine whether demographic and SRH variables vary relative to school (cluster). The psychometric properties of scales will be explored, and confirmatory factor analyses (CFA) for scales will be conducted. Finally, structural equation models (SEM) will be developed based on the multi-level components derived from the Ecological Systems Theory model upon with the N/E was built. CFAs and SEMs will be conducted using Mplus software.

3.1.5 Randomization of schools. The 5 schools that AI youth from Fort Peck attend are the clusters to be randomized into the intervention, with all schools eventually being randomized to the intervention. Students and their parents/legal guardians will be recruited for baseline participation prior to randomization of the sites.

²Woertman W et al. Stepped wedge designs could reduce the required sample size in cluster randomized trials. *J Clin Epidemiol.* July 2013;66(7):752-758.

³Kaufman C et al. Effectiveness of Circle of Life, an HIV-preventive intervention for American Indian middle school youths. *Am J Public Health.* June 2014; 104(6):e106-e112.

⁴Fitzmaurice G, Laird N, Ware J. Generalized Linear mixed effects Models in *Applied Longitudinal Analysis*. Hoboken, NJ: John Wiley & Sons Inc.; 2004.

Schools will be randomized to the intervention following baseline data collection using a single sequence random assignment to clusters that will determine order of intervention receipt.⁵

3.1.6 Generalized linear mixed-effects models. To test for effectiveness of the N/E intervention across all hypotheses under Aim 2, the generalized linear mixed-effects models (GLMM) will be used to model binary primary and secondary outcomes (condom use under H1, condom use and other sexual risks under H2) and continuous tertiary outcomes (H3) in the data. The GLMM allows for individual-level binary and continuous responses to be modeled, key covariates to be controlled for, the specification of autocorrelation within individuals, and clustering by school. The GLMM is also the most frequently employed analytic method to adjust for the longitudinal nature of SWDs,⁶ and it was chosen over the Generalized Estimating Equations (GEEs) because GEEs show inflated Type 1 error rates when the number of clusters is small, as is the case with the number of schools at Fort Peck. Hussey and Hughes proposed a mixed-effects regression approach for the SWD-CRT design,⁷ where:

$Y_{ijl} = \mu + \beta_j + \theta X_{ij} + u_i + e_{ijl}$, and where $u_i \sim N(0, \sigma_u^2)$; $e_{ijl} \sim N(0, \sigma_e^2)$, with β_j =the fixed effect of time, X_{ij} =intervention (0,1 or dose representation), θ =intervention effect, u_i =random effect for cluster, and e_{ijl} =residual for i clusters, j time periods, and l adolescents. Y_{ijl} will be modeled for SRH outcomes, and interpreted in terms of a contrast of the log odds of response relative to AI youths with similar values for unobserved random effects. In order to test for changes in the tertiary outcomes, we will specify Y_{ijl} as continuous response outcomes. STATA statistical software will be used to conduct GLMMs. However, SAS will be used if more complex specification of the intraclass correlation becomes necessary.

3.1.7 Analysis of focus group data. Focus group data will be transcribed and coded using a partially inductive procedure. First, all transcript data will be open coded (line-by-line coding). The open codes will be pre-sorted based on whether participants are responding to acceptability or fidelity prompts. Within each implementation domain, axial codes will be developed to group the open codes, and the team will meet to discuss how axial codes saturate the pre-defined acceptability and fidelity categories. Transcripts will be coded using Atlas.ti software.

3.2 Qualitative Data Analysis. The systems level component and the FAS evaluation component of N/E will be analyzed using content analysis. Common themes will be identified from the two respective sets of data collection instruments. Coding will proceed in stages. A topical indexing scheme will be developed with input from the community advisory board members to identify the text pertaining to particular topics relevant to the systems level and FAS components of N/E. The software program, Atlis.ti will be used to construct and organize a topical indexing system of codes identifying sections of text that capture the central concepts of interests. Then, content coding will be developed by the research team with advice from the community advisory board to capture the content, themes, or sentiment of responses within topics. The community advisory board members will receive copies of the content coding and the content, themes, and sentiment of responses for each of the themes identified in the qualitative data collection forms. Members of the research team, including the community advisory board, will individually identify themes from all text pertaining to a specific topic are related to N/E's AIMS 2 and 3 in order to then assist the research team in developing codes to be analyzed using Atlis.ti. The codes will be reviewed and approved of by the community advisory board prior to analysis. The coding reliability for the content coding will be determined through check coding of at least 20% of the randomly chosen text within major topical categories. Once the data are coded, the themes

⁵ Esserman D, Allore HG, Trivison TG. The Method of Randomization for Cluster-Randomized Trials: Challenges of Including Patients with Multiple Chronic Conditions. *International journal of statistics in medical research*. 2016;5(1):2-7. doi:10.6000/1929-6029.2016.05.01.1.

⁶ Barker D, McElduff P, D'Este C, Campbell MJ. Stepped wedge cluster randomized trials: A review of the statistical methodology used and available. *BMC Med Res Methodol*. 2016;16:69.

⁷ Hussey M, Hughes J. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials*. February 2007;28(2):182-191

and patterns will be summarized and interpreted. Coded text will be used to identify illustrative quotes from the qualitative data collection materials.

SECTION 4: STUDY INTERVENTION ADMINISTRATION OF DATA COLLECTION

N/E is a mixed methods study involving quantitative and qualitative methodology. There are four data collection components to *N/E*: 1) student survey (quantitative); 2) parent survey (quantitative); 3) systems level tracking (qualitative); and 4) fidelity, acceptability and sustainability evaluation (qualitative). The student survey, parent survey and systems level tracking data collection are described in section 4.1. The fidelity, acceptability and sustainability evaluation data collection is described in section 4.2.

4.1. *N/E* Intervention Components: The intervention components and corresponding modes of data collection to test efficacy of the four aspects of our intervention are shown in the table below. The left column indicates the intervention component, while the right column indicates the type of data collection and the timeline of data collection.

Intervention Component	Types of Data Collection and Timeline
Individual level: Native Stand	<ul style="list-style-type: none"> • Student Surveys: baseline, 3 months, 9 months, 12 months
Family level: Native Voices	
Community level: Cultural Mentoring	
Systems level: Enhancement of the coordination and implementation of SRH services at Fort with the Fort Peck Epi Team	<ul style="list-style-type: none"> • Parent Surveys: baseline, 9 months, 12 months • Barriers and Facilitators Discussion Group: yearly • Coordination & Implementing Monitoring Plan Tracking Log: quarterly

Subsequent to randomization of the 5 area schools to the intervention, there will be a baseline data collection from the middle of March to June 2019, followed by three waves of implementation and concurrent data collection over the next 3 years. For a visual picture of how these intervention components and methods of data collection fit into an overall Timeline, please see our Trial Timeline in the appendix.

4.1.1. For the student and parent/legal guardian participating in *N/E*, there are 2 forms of data collection: a student survey and a parent/legal guardian survey. Ms. FireMoon, a part-time assistant, and the *N/E* school outreach coordinator will oversee both surveys' administration. The student surveys and parent/legal guardian surveys will be completed using Research Electronic Data Capture or "REDCap." REDCap is a secure web application for building and managing surveys and databases. The students and parents will take the survey on iPads that have the mobile application version of REDCap installed on the tablets. The mobile app version of REDCap collects data offline to be uploaded to an online, secure database once a secure wifi location is reached. Deidentified data will be stored virtually on the REDCap server and available for download to Genevieve Cox, Paula Firemoon, Michael Anastario, Rachel Hallum-Montes and Beth Rink. Only Paula Firemoon, the *N/E* outreach coordinator, and Genevieve Cox will have access to names linking students and parents to their records during data collection and intervention implementation. These files will be kept in a locked file cabinet by Genevieve Cox at MSU after data collection.

From Years 2-4, 456 students and one of their parents/legal guardians will participate in *N/E*'s data collection. Student surveys for baseline, 3, and 9 months will be administered during regularly scheduled classes in an assigned classroom by Ms. FireMoon, the assistant, and *N/E*'s outreach coordinator. Baseline data collection will begin in March 2019 for all schools and parents included in the intervention. Groups of 20 students at a time will be appropriately spaced in the classroom in order to ensure privacy, and survey instructions will be presented to students prior to REDCap administration. Ms. FireMoon, the assistant, and the *N/E* outreach

coordinator will thoroughly review the assent form with the students, which will include a description of N/E, types of questions that will be asked, and potential risks and benefits of participating in N/E. All students will be reminded that they can withdraw at any time without consequences. Prior similar procedures have been successfully used by Dr. Rink and Ms. FireMoon for data collection in the Fort Peck schools with AI youth. For students who graduate from high school prior to the 12-month follow-up, they and their parent/legal guardian will be contacted by Ms. FireMoon to complete the 12-month follow-up (during evening hours) at the high school from which they graduated following the same procedure described above. Although data collection for the students has been designed to coincide with the school year, the same procedures will be followed if the data collection occurs when school is not in session.

Wave 1 data collection will commence in December 2019 with 1 school after students have begun receiving the Native Stand and Cultural Mentoring components of the intervention during the school year. Wave 1 9-month follow-up will take place at the end of the school year in May/June 2020 as the intervention is completed. The Wave 1 12-month follow-up will take place at the beginning of the next school year in September 2020. Wave 2 (2 schools) and Wave 3 (schools) will follow the same procedures and pattern of timeline of data collection.

The parent survey will be administered during evening hours at the high school by Ms. FireMoon, the assistant, and N/E's outreach coordinator. All baseline parent data will be collected in Fall 2019. We will use the same REDCap administration procedures for parents/legal guardians that are described for students above. Ms. FireMoon, the assistant, and the N/E outreach coordinator will review the consent forms with the parents/legal guardians to ensure their understanding of the purpose of N/E, types of questions they will be asked, and the study's potential risks and benefits. All parents/legal guardians will be reminded that they can withdraw themselves and/or their child at any time without consequences. Wave 1 (parents of first school) parent 9-month follow up will take place in spring of 2020. Wave 1 parent 12-month follow-up will take place in Fall 2020. Wave 2 (parents of schools 2 and 3) and Wave 3 (parents of schools 4 and 5) will follow the same procedures and pattern of timeline of data collection. Data Safety & Monitoring Plan describes participant safety and support plans.

4.1.2 For the systems-level component of N/E, there are 2 forms of data collection: a barriers/facilitators discussion guide, and a coordination and implementation monitoring plan tracking log.

These 2 forms of data collection span the 8 service domains relative to improving SRH services for adolescents as outlined by the CDC. The barriers/facilitators discussion guide will be administered in a group discussion format to the Epi Team at baseline and at 12 months during a standing monthly meeting held at the Fort Peck Tribal Headquarters to assess the factors that impede or strengthen the provision of SRH services for AI youth at Fort Peck. The Epi Team's discussion of the barriers/facilitators will be recorded and transcribed. Based on findings from the barriers/facilitators guide, a coordination and implementation monitoring plan will be developed in the form of a tracking log, in order to monitor improved coordination and provision of SRH services. The coordination and implementation monitoring plan tracking log will be completed as part of the baseline data collection and tracked quarterly during a regular monthly meeting of the Epi Team. Dr. Rink and Ms. FireMoon will be the primary research staff—with assistance from two of N/E's consultants, Ms. Adriann Ricker and Dr. Rachel Hallum-Montes—to collaborate with the Epi Team in completing the barriers/facilitators discussion guide, developing the implementation monitoring plan, and tracking the plan's progress toward increasing access to SRH services for AI youth. No identifying data or participants will be collected.

4.1.3 Incentives: Incentives for the students and parents/legal guardians are based on discussions with N/E's Community Advisory Board and members of the FPCC research team, as well as Dr. Rink's prior experience with research studies involving Indigenous communities. Students will receive \$10 at the baseline, 3-month, and 9-month data collections and \$20 at the 12-month data collection. Parents/legal guardians will receive \$10 at the baseline and 9-month data collections and at each of the 4 sessions of Native Voices, plus \$20 at the

12-month data collection. Similar incentives for students and parents have been previously successful. Epi Team members will not receive incentives for participation in N/E, as it is part of their tribal employment responsibilities.

4.2 Fidelity, Acceptability and Sustainability Data Collection. Fidelity recommendations from the National Institutes of Health Behavior Change Consortium will be implemented across the 5 areas of study design, component leader training, delivery of treatment, receipt of treatment, and enactment of treatment skills. The Fidelity, Acceptability, and Sustainability (FAS) of the N/E intervention will be emphasized with a variety of internal processes and data collection methods. The left column describes the FAS component, while the right column describes the corresponding type of data collection and timeline of data collection.

Fidelity, Acceptability, and Sustainability Component	Types of Data Collection and Timeline
Community Advisory Board (CAB) meetings	<ul style="list-style-type: none"> • CAB FAS Meeting Form: quarterly • CAB meeting notes: quarterly
Team-wide meetings	<ul style="list-style-type: none"> • Team-wide meetings FAS Form: bi-monthly
Consistency of staff training	<ul style="list-style-type: none"> • Staff training evaluation log: yearly
FAS of coordination/implementation enhancement of Epi Team	<ul style="list-style-type: none"> • Fidelity Reach Log/Staff Field notes: monthly
Intervention implementation of Native Stand, Native Voice, and Cultural Mentoring	<ul style="list-style-type: none"> • Fidelity Reach Log/Staff Field notes: each day of intervention
Community level FAS	<ul style="list-style-type: none"> • 8 Focus Groups (2 youth, 2 parent, 2 professionals): yearly beginning in Year 3 (Total of 24 Focus Groups)

4.2.1 FAS Data Collection: In consultation with Dr. Hallum-Montes, Dr. Rink, Dr. Cox, and Ms. Firemoon developed four forms to collect FAS data during the implementation of the intervention.

Forms: 1.) The “Community Advisory Board Meeting Form” will be collected once per quarter after each meeting of the CAB. It will document the barriers and facilitators to intervention implementation discussed at CAB meetings, any social, environmental, political, or bureaucratic contextual factors such as the death of an elder or Tribal Council election year, that may have inhibited or facilitated intervention implementation, and any suggestions to mitigate these barriers the CAB discusses. CAB meeting notes will also be taken during each meeting. 2.) The “Whole Team Meeting Form” will document bi-monthly meetings that include Paula Firemoon, Beth Rink, Adriann Ricker, Ramey Growing Thunder, the N/E outreach coordinator, the Cultural Mentor outreach coordinator, and Genevieve Cox. This form will include any barriers and facilitators to intervention implementation discussed, contextual factors (social, environmental, political, or bureaucratic) discussed, suggestions, and who will be responsible for implementing these suggestions. 3.) The “Staff Training Evaluation Log” will be collected yearly and documents who has been trained, what procedures were followed during training, problems encountered during trainings, and any feedback from the trainings. 4.) The “Fidelity Reach Log and Field Notes” form includes documenting the delivery of the intervention and any field observations study staff note. It will document the date of the intervention, the length of time the intervention was delivered, specific modules delivered, and any barriers and facilitators to the delivery of the intervention. The outreach coordinator will also document any environmental, social, political, or bureaucratic barriers or facilitators and suggested solutions to the intervention delivery. With the exception of names of staff trained, no identifying data will be collected. These files will be kept in a locked file cabinet by Genevieve Cox at MSU after data collection.

In addition to the 4 FAS forms, we will implement 8 focus groups at 12 months from inception of the intervention for each year of the 3 years of planned intervention implementation (a total of 24 focus groups). The focus groups will include 6 to 8 individuals per group. The 8 focus groups will consist of 2 focus groups with youth, 2 focus groups with parents, 2 focus groups with the cultural mentors, and 2 focus groups with professionals from schools, agencies, and health care organizations that are involved in N/E. The focus groups will be recorded and transcribed. Written consent will be obtained from the adults participating in the fidelity and acceptability focus groups. Written consent and assent will be obtained from the parents/legal guardians and their child, respectively, in order for the child to participate in the focus groups. Focus group participants will receive a \$20 incentive. No identifying data will be collected.

SECTION 5: SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria. To be eligible for inclusion in N/E, students must be: 1) 15 to 18 years old; 2) a registered member of a federally recognized tribe or an associate tribal member; and 3) a resident of Fort Peck with a parent/legal guardian. For inclusion in the systems-level component of N/E, only those staff members who sit on the Epi Team as representatives of their respective agencies are eligible. Written informed consent will be obtained from the head of each agency represented on the Epi Team and the staff member participating in the Epi Team.

4.2 Exclusion Criteria. Exclusion criteria are minimal due to the CAB's value of inclusion in N/E. Exclusion criteria include: 1) not meeting the aforementioned inclusion criteria; and 2) having a medically identified physical or cognitive impairment that would impede their understanding of and participation in the educational content and activities of *Native Stand*, *Native Voices*, and the cultural mentoring program.

4.3 Study Enrollment Procedures. Students and their parent/legal guardian will be recruited from each of the study's 5 schools. Based on discussions with school personnel and our previously successful recruitment strategies, recruitment will occur via flyers posted in the schools, letters to the parents, parent-teacher meetings, and word of mouth. Additionally, a parent/legal guardian session that provides an overview of N/E, the content and format of the intervention components, and risks and benefits of participation will be held at each of the study's 5 schools. Students and their parents/legal guardians, and students from each cluster, will be recruited for participation at baseline. Students and their parents/legal guardians will be recruited for baseline participation **prior to randomization of the sites**. Students and parents/legal guardians will be assigned unique study identification numbers. No persons who refuse to participate in the study, in whole or in part, will be coerced to engage in any study activity. After written consent and assent is obtained from the parent/legal guardian and child, respectively, they will be enrolled in the study.

SECTION 5: HUMAN SUBJECTS

5.1 Institutional Review Board Approvals. The study has approval from the Fort Peck Institutional Review Board and the Montana State University Institutional Review Board. In addition, the study has been registered with ClinicalTrials.gov. These aforementioned approvals are in agreement with the conditions for approval to conduct human subjects research as outlined in our Notice of Grant Award from the National Institute of Minority Health & Health Disparities.

5.2. Human Subjects' Characteristics. There three groups participating in the study in which data will be collected include: 1) 15 to 18 year old youth; 2) a parent/legal guardian; and 3) members of the Fort Peck Epi Team.

5.3. Data Sources for Human Subjects Based on Intervention Levels. Our study includes four levels of intervention:

*Nenunkumbi/Edahiyedo ("We Are Here Now"):
A Multi-level, Multi-component Sexual and Reproductive Health Intervention for American Indian Youth*

Study Protocol and Statistical Analysis Plan

1) Individual Level. Native Stand is a school-based, 27-module STI-, HIV-, and teen pregnancy-prevention curriculum, originally developed for rural white youth and adapted for Native youth in 2008. For our study, an adaptation of Native Stand will be implemented over 9 months in the 5 tribal high schools to educate Fort Peck tribal youth on sexual risk behavior prevention strategies by tailoring and reducing the 27 modules into 18 modules, as well as including specific community-relevant traditional and contemporary cultural lesson plans. Trained project staff will deliver Native Stand in school classroom settings during the school year as part of each school's curriculum. American Indian students only will be recruited for Levels 2 and 3 and for data collection.

2) Family Level. Native Voices is a video-based HIV/STI prevention intervention designed for AI adolescents, which includes condom use, negotiation skills, group discussion, and role playing. Native Voices will be adapted from 1 module into 4 modules, as recommended by the creators of Native Voices for curriculum adaptations involving family members, and will involve students and one of their parents/legal guardians. Our adaptation of Native Voices promotes discussions between the students and their parent/legal guardian regarding STI, HIV, HCV, and pregnancy prevention relevant to the Fort Peck tribal community. Ms. FireMoon will implement Native Voices to groups of 10 students and their parents/legal guardians at one time at the local high school for 2 hours in the evening. Native Voices' 4 modules will be implemented over 9 months.

3) Community Level. The third level of our study is a cultural mentoring component that pairs AI youth with older adults and elders to discuss traditional American Indian beliefs and practices about reproductive health. To our knowledge, no mentoring programs have been designed for AI youth that specifically address sexual and reproductive health issues. The mentoring program is based on Assiniboine and Sioux traditional knowledge and the National Mentoring Partnership standards for mentoring. The mentoring program was designed specifically for Fort Peck youth by the Fort Peck Tribes' Language and Cultural Department and has been in existence for 5 years. Our study integrates this cultural mentoring program into our study's overall framework. Our cultural mentoring program will include older male and female tribal members from the Assiniboine and Sioux tribes. The older adults will be paired with the youth participating in the intervention by gender and tribal affiliation. Students participating in Native Stand and Native Voices with their parent/legal guardian will meet monthly over the course of 9 months one-on-one with their mentor and monthly in mentor mentee small groups. Topics addressed in the cultural mentoring program include overall information on Assiniboine and Sioux cultural beliefs, values, and ceremonies, as well as more specific information on Assiniboine and Sioux cultural beliefs and values regarding sex, having children, parenting, and relationships.

4) Systems Level. The fourth level of our study is a community-level strategy that involves mobilizing a network of education, health care, and social service agencies at Fort Peck to coordinate reproductive health services for 15- to 18-year-old AI youth over a 12-month period. The systems-level approach will utilize existing tribal infrastructure by enhancing the work of the established Fort Peck Tribal Epidemiology Team (Epi Team). The Epi Team is a local committee made up of the Fort Peck Tribal Health Department; Indian Health Service (Poplar Service Unit and Wolf Point Service Unit); the Roosevelt County Health Department; and school nurses from the Fort Peck Health Promotion and Disease Prevention Program. The Epi Team meets monthly and has been in existence for 15 years with the purpose of monitoring diseases on the reservation and the health status of the Assiniboine and Sioux tribes. As part of N/E, the Epi Team is tasked with improving the coordination and implementation of STI, HIV, and HCV screening, condom distribution, contraceptive services, and pregnancy testing on the Fort Peck Reservation.

5.3.1. Data Collection Materials for Human Subjects. For the individual-, family-, and community-level components of N/E, there are two forms of data collection: a student survey administered at baseline and at 3, 9, and 12 months after intervention inception, and a parent/legal guardian survey administered at baseline and at 9 and 12 months after intervention inception. The student survey will assess participation in Native Stand, Native Voices, and the cultural mentoring program. The parent survey will assess participation in Native

Voices. Ms. FireMoon and the study's outreach coordinator will oversee the administration of the student surveys and the parent/legal guardian surveys. The student surveys and parent/legal guardian surveys will be completed utilizing REDCap. Between Years 2-4, 456 students and one of their parents or legal guardians will participate in N/E's data collection. Student surveys for baseline, 3 months, and 9 months will be administered to groups of 20 students at a time during regularly scheduled classes in an assigned classroom by Ms. FireMoon and the study's outreach coordinator. During data collection, groups of 20 students will be appropriately spaced in the classroom in order to ensure privacy, and survey instructions will be presented to students prior to REDCap administration. Ms. FireMoon and the study's outreach coordinator will thoroughly review the assent form with the students at the baseline data collection, which will include a description of N/E, types of questions that will be asked, and potential risks and benefits of participating in N/E. All students will be reminded that they can withdraw at any time without consequences. For students that graduate from high school prior to the 12 months data collection, they will be contacted by Ms. FireMoon directly to complete the 12 months data collection (during evening hours) at the high school they graduated from following the same procedure described above. This same procedure will be followed if the data collection time point occurs for some reason when school is not in session. The parent survey will be administered during evening hours at the high school in an assigned classroom by Ms. FireMoon and the study's outreach coordinator. We will use the same REDCap procedures for parents/legal guardians that are described for youth above. In addition, written consent will be obtained from the parents/legal guardians prior to their participation in the study. Ms. Firemoon and the study's outreach coordinator will review the informed consent with the parents/legal guardians at the time of data collection.

For the systems-level component of N/E, there are two forms of data collection: a barriers/facilitators discussion guide and a coordination and implementation monitoring plan tracking log. These two forms of data collection span the 8 service domains relative to improving SRH services for adolescents as outlined by the Centers for Disease Control and Prevention (CDC). The barriers/facilitators discussion guide will be administered in a group discussion format to the Epi Team at baseline and at 12 months during a standing monthly meeting held at the Fort Peck Tribal Headquarters to assess the factors that impede or strengthen the provision of SRH services for AI youth on the Fort Peck Reservation. The Epi Team's discussion of the barriers/facilitators will be recorded and transcribed. Based on findings from the barriers/facilitators guide, a coordination and implementation monitoring plan will be developed in the form of a tracking log in order to monitor improved coordination and provision of SRH services. The coordination and implementation monitoring plan tracking log will be completed as part of the baseline data collection and tracked at 3, 6, 9, and 12 months during a regular monthly meeting of the Epi Team. In collaboration with the Epi Team, Ms. FireMoon, Ms. Adriann Ricker, and Dr. Rink will complete the barriers/facilitators discussion guide, develop the implementation monitoring plan, and track the plan's progress toward increasing access to sexual and reproductive health services for American Indian youth on the Fort Peck Reservation.

All students attending each school will be eligible to participate in the individual-level Native Stand curriculum, as it will be incorporated into that school's regular curriculum. In order to be eligible for inclusion in the family and community-level components of N/E and the data collections, students must be: 1) 15 to 18 years old; 2) a registered member of a federally recognized tribe or an associate member; 3) a resident of the Fort Peck Reservation with a parent/legal guardian; and 4) enrolled at one of the five schools participating in N/E.

Exclusion criteria are minimal due to the value the CAB places on inclusion in N/E's program implementation. Exclusion criteria include 1) not meeting the aforementioned inclusion criteria, and 2) having a physical or cognitive impairment that would impede the student's understanding of and participation in the content of Native Stand, Native Voices, and the cultural mentoring program. Study-enrolled students must agree at the outset to participate in Native Stand, Native Voices, and the cultural mentoring program, and agree to complete the survey at baseline and at 3, 9, and 12 months during and shortly after their cluster's program. Parents/legal guardians must also agree to participate in Native Voices and complete the parent/legal guardian survey at baseline and at 9 and 12 months. No persons will be coerced to engage in any study activity, and anyone may

refuse to participate at any time. After written consent and assent are obtained from the parents/legal guardians and their children, respectively, they will be enrolled in the study. For inclusion in the systems-level component of the study, only those staff members who sit on the Epi Team as representatives of their respective agencies are eligible. Written informed consent will be obtained from the head of each agency represented on the Epi Team and the staff member participating in the Epi Team.

If at any point in the study a student discloses abuse, they will be referred to the appropriate person or organization. For example, a research participant who is under the age of 18 and in school who discloses that he or she is being abused at home will be referred to the counselors in the school for assistance, with the possibility of joint reporting to Child Protective Services. Students will be informed during the informed consent process that any abuse they may disclose will be reported, since the members of the research team and the interviewers are mandated reporters.

Another form of data collection that involves human subjects is related to Aim 3 of our study, which is to evaluate the fidelity and acceptability of N/E. As part of Aim 3 we will conduct focus groups. We will implement 8 focus groups at 12 months from inception of the intervention's curricular components for each year of the 3 years of planned intervention implementation (a total of 24 focus groups). The focus groups will include 6 to 8 individuals per group. The 8 focus groups will consist of 2 focus groups with youth, 2 focus groups with parents, 2 focus groups with the cultural mentors, and 2 focus groups with professionals from schools, agencies, and health care organizations that are involved in N/E. Written consent and assent will be obtained from adults, parents/legal guardians, and youth, respectively. Focus groups will be recorded and transcribed. No names or other identifying information, such as an address, will be included on the transcripts. However, age and gender will be recorded. After each focus group, the focus group facilitator will check the audiotapes for clarity. Clear audiotapes will be transcribed. Audiotapes that are not sufficiently clear, or do not have adequate volume to transcribe, will not be transcribed. Instead, responses typed or directly written down by the focus group guide during the interview will be used as the transcript for content analysis. Names of students or others identified in the transcripts will be blacked out in order to ensure confidentiality.

5.3.2. List of Data Source Materials (Table 2 below).

Student Survey: To assess students' participation in N/E, we draw from several existing measurements that have been implemented and validated in research studies with AI youth. Primary outcome measure: Condom use will measure frequency of condom use relative to frequency of sex during sexual intercourse using questions derived from the Risk Behavior Assessment. Secondary outcome measures: These will include the number of sex partners; age of onset of sexual intercourse; frequency of sexual intercourse; pregnancy history; frequency and type of birth control used during sexual intercourse relative to the frequency of sexual intercourse; and frequency and types of substance use (cigarettes, marijuana, alcohol, and methamphetamine). Tertiary outcome measures: Parent/legal guardian communication is measured by the frequency and types of SRH topics that parent/legal guardian and child discussed. Cultural identity is measured using two established measurements: One measure assesses the extent to which a student identifies with his or her American Indian culture and feels cultural pride, and the other measure assesses frequency and type of participation in cultural activities. Access to SRH services is measured by frequency and type of SRH service used (ever been tested for STIs and follow-up, ever been tested for HIV and follow-up, ever been tested for HCV and follow-up, ever been pregnant/gotten someone pregnant and follow-up). Other variables to be measured in N/E that assess attitudes, intentions, skills, and mental health are: Motivation to avoid STIs, HIV, HCV, and pregnancy, as measured by asking students how important it is to them to keep themselves (or someone else) from getting an STI, HIV, and HCV, and how important it is to them to keep from getting pregnant or getting someone pregnant. Intention to use condoms and/or birth control is measured by asking students how likely it is they will use condoms and/or birth control the next time they have sexual intercourse. Intention to abstain from sex is measured by asking students how likely it is that they will not participate in sexual intercourse. Condom and birth control use self-efficacy is measured by assessing

confidence in one's ability to use condoms and birth control. Refusal skills regarding sex are assessed by how strongly students believe they can say no to sex. Knowledge about STIs, HIV, HCV, pregnancy, and healthy relationship characteristics are measured using true/false/don't know questions. Mental health is assessed using two established measures: One measure assesses depression using the C-ESD, and the other measurement assesses exposures to stressful life events by assessing lifetime occurrences of a series of negative events. Standard demographic measures in the student survey are age, gender, sexual orientation, school, and highest grade completed.

Parent/Legal Guardian Survey. The parent/legal guardian survey is based on parents'/legal guardians' participation in Native Voices. It includes a list of SRH topics about which the parent/legal guardian has spoken to the child and the frequency of times discussed. The parent/legal guardian measures have been validated in previous studies evaluating parent/child SRH communication and have been used by Dr. Rink in her Greenland studies. The SRH topic list and frequency is the same as in the student survey, only adapted for parents/legal guardians. Standard demographic measures included in the parent/legal guardian survey are age, gender, marital status, highest grade completed, and occupation.

Barriers/Facilitators Discussion Guide. The barriers/facilitators discussion guide is a qualitative assessment using open-ended questions that address the factors impeding and facilitating SRH services for AI youth on the Fort Peck Reservation. The guide is based on the 8 service domains for evidence-based clinical practices outlined in the CDC's Contraceptive and Reproductive Health Services for Teens: Evidence-based Clinical Best Practices Guide(80-82)—namely, contraceptive access; provision of hormonal contraception/IUD; emergency contraception; cervical cancer screening; STI/HIV/HCV testing and treatment; cost, confidentiality, consent; health center infrastructure; and health center environment.

Coordination and Implementation Monitoring Plan Tracking Log. The tracking log will monitor the progress toward completion of the 8 SRH service domains identified from the barriers/facilitators discussion guide and corresponding evidence-based clinical practice elements.

Focus Groups. Data collection related to Aim 3 of our study, which is to evaluate the fidelity and acceptability of N/E, includes a focus group guide, as described above. The Aim 3 focus groups will include questions such as what experiences/activities they liked and/or did not like about the intervention, what educational information they did and/or did not like about the intervention, and what recommendations they have for improving the intervention.

Table 2. N/E Measures.

Data Collection Instruments and Measures	Data Collection: Baseline & Months				Description of Measures	
Student Survey	Base	3	9	12	Number of Items; Scale Anchors; Benchmark Values	
Primary Outcome Variable						
Proportion of condom use during sexual intercourse (SI)	X	X	X	X	2 items; number of times condom used relative to number of times had SI	
Secondary Outcome Variables						
Age of onset of sexual intercourse	X	X	X	X	2 items; ever had SI & age at first SI	
Number of sex partners	X	X	X	X	2 items; lifetime & past-month sex partners	
Frequency of sexual intercourse	X	X	X	X	1 item; frequency of SI in past month	
Pregnancy history	X	X	X	X	1 item; number of pregnancies	
Type & frequency of birth control (BC) during sexual intercourse	X	X	X	X	3 items; type of BC use and number of times BC used during SI	
Type & frequency of substance use (SU) during sexual intercourse	X	X	X	X	1 item measure SU with SI; 5 items measure lifetime and past month SU	
Tertiary Outcome Variables						
Type & frequency of parent/legal guardian–child SRH communication	X	X	X	X	24 items Likert scale; higher score = higher communication	
Cultural identity & participation in cultural activities	X	X	X	X	3 items cultural identity ($\alpha = .75$); 2 items cultural activities engagement ($\alpha = .46$)	
Type & frequency of SRH services	X	X	X	X	9 items; frequency, type, and follow-up of SRH services used	
Other Variables						
Motivation to avoid STIs, HIV, HCV, & pregnancy	X	X	X	X	Up to 9 items; 1 (very true) to 5 (very untrue); 1 = more positive attitude/motivation	
Condom & birth control use intention & self-efficacy	X	X	X	X	4 items per intention; 1 (very true) to 5 (very untrue); 1 = higher intention; 6 self-efficacy items; 1 (very easy) to 4 (very hard); 1 = high self-efficacy	
Abstinence	X	X	X	X	3 items; 1 (strongly disagree) to 4 (strongly agree); 4 = more supportive of teen abstinence	
Refusal skills regarding sex	X	X	X	X	7 items; 1 (I definitely can say no) to 5 (I definitely can't); 1 = stronger refusal skills	
Knowledge of STIs, HIV, HCV, pregnancy, & health relationships	X	X	X	X	Range of 4 to 10 items per topic; True/False/DK; Average proportion of questions correct	
Depression (CES-D) & exposure to stressful life events	X	X	X	X	CES-D — 7 items ($\alpha = .80$); Life Events — 24 items; Yes/No; number of events observed	
Student Demographics						
Age, gender, sexual orientation, school, highest grade completed	X	X	X	X	4 items	
Parent/Legal Guardian Survey						
Type & frequency of parent/legal guardian–child SRH communication	X		X	X	24 items Likert scale; higher score = higher communication	
Parent/Legal Guardian Demographics						
Age, gender, marital status, highest grade completed, occupation	X		X	X	5 items	
Barriers/Facilitators Discussion Guide						
8 Service Domains for Evidence-Based Clinical Best Practices	X			X	Open-ended questions about barriers/facilitators for: contraceptive access, provision of hormonal contraception/IUD, emergency contraception, cervical cancer screening, STI/HIV/HCV testing and treatment, cost confidentiality, consent, health center infrastructure, & health center environment.	
Coordination & Implementation Monitoring Plan Tracking Log						
8 Service Domain Elements	X	X	X	X	X	Tracks action steps, timeline, and responsible party

5.4 Potential Risks

There may be minor risks to agreeing to participate in N/E. Student and parent/legal guardian participants may be asked some questions that make them feel uncomfortable, sad, or confused (e.g., questions about sexual risk behaviors). For participants in the systems-level component of the study that evaluates the enhancement of the coordination of SRH services, we anticipate low to no risks, since none of the data being collected will be of a personal nature. For Aim 3, which uses focus groups as one method of data collection to evaluate the fidelity and acceptability of N/E, we also anticipate low to no risk, since none of the data being collected will be of a personal nature. All study participants will be informed that they may choose to stop their participation in N/E at any time or decline to answer a particular question asked of them on a data collection instrument or during a data collection process. We will inform study participants that the study is voluntary and that they can withdraw from the study, by stating that they want to do so, at any time over the course of the study.

5.4.1. Adequacy of Protection Against Risks

A. Recruitment and Informed Consent

The high schools in Frazer, Wolf Point, Poplar, Brockton, and Culbertson will serve as the primary recruitment sites for our study. Based on discussions with school personnel and our previously successful recruitment strategies, recruitment will occur via flyers posted in the schools, letters to the parents, parent-teacher meetings, and word of mouth. Additionally, a parent/legal guardian session that provides an overview of N/E, the content and format of the intervention components, and risk and benefits of participation will be held at each of the study's 5 schools. Students and their parents/legal guardians from each cluster will be recruited for participation at baseline (Q2 of Year 2). At the time of the student data collection at baseline, Paula FireMoon

and the study's outreach coordinator will thoroughly review the assent form with the students, which will include a description of the N/E curricular components, types of questions that will be asked in the data collection, and potential risks and benefits of participating in N/E. All attempts will be made to help the students understand the nature of the study. Paula FireMoon and the study's outreach coordinator will thoroughly review the consent forms with the parents, which will include a description of N/E, types of questions that will be asked, and potential risks and benefits of participating in N/E. Parents will provide informed consent for their child as well as for themselves prior to their participation in the Native Voices curriculum. For the systems-level component, Epi Team members will complete an informed consent at the time of the first barriers and facilitators discussions in Year 2. If members change from one such discussion to the next, new informed consents will be collected as needed. For the Aim 3 focus groups, informed consent will be obtained from the mentors or the professionals representing agencies prior to their participation in the focus groups as key stakeholders. Consent and assent will be obtained from parents/legal guardians for their participation in a parent group, and from parents/legal guardians and their children, respectively, for the children's participation in a children's focus group. All study participants, both adults and children, will be reminded that they can withdraw at any time without consequences. No study participant will be coerced to participate in the study, in whole or in part. Human subjects approval has been received from the Fort Peck IRB for the Year/Aim 1 refining, tailoring, and finalizing the intervention design. At that point, new applications to the Fort Peck IRB and the MSU IRB will receive approvals prior to study start.

B. Protection Against Risk

Because N/E involves children ages 15 to 18 years old, we will ensure that parents/legal guardians understand the research protocol and are able to provide informed consent for themselves and their participating children in this minimal-risk intervention study. To preserve confidentiality, all data collection forms will be coded with a unique identifier. All of the project data, including the audiotapes and transcripts, will be labeled with study identification numbers and stored separately from the informed consent forms. Consent forms will be kept in a locked file cabinet in Paula FireMoon's office at Fort Peck Community College, which has a combination lock on the door that only Paula FireMoon knows. All survey data will be stored in a password-protected file on a password-protected computer at Fort Peck Community College in Paula FireMoon's office. Focus group documents will be uploaded onto MSU's Box server, a password-protected cloud data storage system. All of the project data—including the audiotapes, transcripts, and interview summaries with study identification numbers—will be stored separately from the informed consent forms in a locked file cabinet in Dr. Rink's locked office at Montana State University, to which only Dr. Rink and the MSU-based research program manager, Genevieve Cox, will have access. Once the focus groups have been transcribed and checked for validation against the audiotapes, the audiotapes will be destroyed in order to ensure no voice recognition. At the end of the project, all of the deidentified data files (though not individual surveys) will be returned to Fort Peck Community College and stored in the Fort Peck research archives in Poplar, Montana, as is required by the Fort Peck IRB. Please note that none of the data returned to Fort Peck Community College will contain a study participant's name or contact information to ensure that personal information collected during the study is not associated with a study participant's name. Data files at Fort Peck Community College will be kept in accordance with federal law regarding research material. Also, the study participants (completing surveys or participating in focus groups) will be informed of where the data will be stored during the informed consent process. All data will be kept in accordance with federal law requirements regarding research material.

SECTION 7: DATA SAFETY MONITORING PLAN

This plan describes the general data and safety monitoring procedures for the proposed research activities, including the responsibilities of the PI, Co-Investigators, and the Community Advisory Board, as well as the reporting of adverse events. This data safety monitoring plan was submitted with our R01 proposal and approved by the review panel, project officer and grants management officer at NIH. Protocols for data safety have also been reviewed and approved by the Fort Peck and Montana State University Institutional Review

Boards.

The principal investigator, Elizabeth Rink, Ph.D., the Fort Peck–based project director Paula FireMoon, M.Ed. (co-investigator), and the Fort Peck Tribes’ Language and Culture Department director Ramey Growing Thunder, MA (co-investigator), will be responsible for knowing and adhering to the cultural protocols and official policies of the Fort Peck Tribes and the five participating high schools; the Fort Peck IRB policies and procedures; and the MSU IRB policies and procedures. Dr. Rink will be the lead on the Fort Peck and MSU IRB correspondences and reports. She will maintain accurate documentation of the Fort Peck and MSU IRB correspondences and reports on her password-protected desktop computer in her locked office at MSU. The PI and the local Fort Peck co-investigators (FireMoon and Growing Thunder), who together will oversee the intervention at Fort Peck, are responsible for documentation and handling of all possible study-related adverse events. They all are experienced in conducting research and implementing and evaluating community based programs with American Indian youth. Rink and FireMoon have experience conducting such research related to sexual and reproductive health. All will assure that data collection and safety monitoring systems are in place and implemented—Mrs. Growing Thunder for the mentoring program and Ms. FireMoon for the other intervention components.

The Data and Safety Monitoring Plan includes the following descriptions:

1. Potential adverse events resulting from participation;
2. Procedures to safeguard against those events;
3. Response procedures for adverse events;
4. Reporting procedures for adverse events;
5. Oversight.

1. Potential Adverse Events Resulting from Participation

- A. Possible violation of confidentiality;
- B. Possible violation of cultural protocols or official policies;
- C. Possible discomfort due to completing data collection tools;
- D. Possible embarrassment in disclosing personal sensitive information;
- E. Possible disclosure of information about intended physical harm to victims, or abuse of children, that would need to be reported to the child welfare agency, and an investigation of the allegations(s) and further action, as indicated, that could ensue;
- F. Possible dissatisfaction with completing the data collection tools;
- G. Possible dissatisfaction with the intervention activities.

2. Procedures to Safeguard Against Adverse Events

All data collection protocols include a form on which the research team will record any problems with the data collection, concerns about the adolescents, or unusual occurrences during the conduct of the intervention or the collection of data. These forms allow the team to quickly review and respond to any possible concerns or adverse effects. The form includes contact information for Rink, FireMoon, and Growing Thunder. One or more of them will always be available during data collection. During phone conferences and meetings (weekly during the intervention periods and monthly otherwise), all problems and concerns will be discussed and processed among themselves, and with other project personnel as needed.

A. Informed Consent: Ms. FireMoon and the N/E outreach coordinator will review the consent forms with the parents/legal guardians at baseline to ensure their understanding of the purpose of N/E, types of questions they will be asked, and the study’s potential risks and benefits. They will be reminded that they can withdraw themselves or their child at any time without consequences. Likewise, Ms. FireMoon and the study’s outreach

coordinator will thoroughly review the assent form with the 456 students to be enrolled, which will include a description of N/E, types of questions that will be asked, and potential risks and benefits of participating in N/E. All students will be reminded that they can withdraw at any time without consequences. After written consent and assent are obtained from the parents/legal guardians and their child, respectively, they will be enrolled in the study. For inclusion in the systems level component of the study, only those staff members who sit on the Epi Team as representatives of their respective agencies are eligible. Written informed consent will be obtained from the head of each agency represented on the Epi Team and the staff member participating in the Epi Team. Written consent and assent will be obtained from the maximum of 192 adult professionals, parents/legal guardians, and youth, respectively, for participation in the 24 planned focus groups. All study participants will be informed of where and how the data will be stored during the informed consent process.

B. Confidentiality and Data Safeguards: To ensure confidentiality, all information will be coded using a unique identification number so that it cannot be associated with any individual. All of the survey data will be labeled with study identification numbers and stored separately from the informed consent forms in a locked file cabinet in Paula FireMoon's locked office at Fort Peck Community College. A master sheet, with individual names and their respective unique study identification numbers, will be kept in a separate locked file that can be accessed only under supervision of the PI or Project Director. The data collection from the student surveys and parent/legal guardian surveys will be downloaded using the RedCap software into the MSU Box server, a file-sharing cloud server, for storage. This is a password protected virtual storage system for de-identified research materials that only specified invited individuals (members of the research team) may view. The audiotapes of the focus groups will be stored separately from the informed consent forms in a locked file cabinet in Dr. Rink's locked office at Montana State University. All other focus group data including the de-identified transcripts, interview summaries, and the results of the content analysis will be stored on the MSU Box server. All data entered into Box as part of the project's computerized database will be identified by unique identification number only. The entire research team and all other project personnel who come in contact with data or with the human subjects of the intervention will sign a formal oath of confidentiality. The information gathered will be used only for scientific, program evaluation, or instructional purposes. No information about the identities of study participants will be published or presented at conferences.

C. Cultural Protocols and Tribal/School Policy Safeguards: Dr. Rink and Ms. FireMoon will be responsible for working with the study's CAB, other investigators, and consultants to ensure that the intervention adheres to the cultural protocols and official policies of the Fort Peck Tribes; the Fort Peck IRB policies and procedures; and the MSU IRB policies and procedures. Tribal elders will be consulted on traditional topics and protocols that cannot otherwise be addressed by Ms. FireMoon, the study's CAB members, and Mrs. Growing Thunder. Dr. Rink and Ms. FireMoon will hold quarterly meetings with the study's CAB. All documents related to N/E will be developed, reviewed, and vetted by the study's CAB members as necessary during the quarterly CAB meetings. Similarly, all data resulting from N/E will be reviewed, interpreted, and approved by the CAB. If necessary, Dr. Rink and Ms. FireMoon will also meet individually with CAB members to discuss the study's research protocols, data collection instruments, and findings. In addition to the CAB-related meetings, Dr. Rink, Ms. FireMoon, and Mrs. Growing Thunder will hold monthly team meetings to discuss the study's research protocols, implementation strategies and progress, research-related documents, data collection procedures, and analysis. Any concerns brought up by the CAB or other members of the research team will be discussed until a resolution is reached.

As part of N/E we will use fidelity and acceptability recommendations from the National Institutes of Health Behavior Change Consortium. These recommendations address study design, component leader training, delivery of treatment, receipt of treatment, and enactment of treatment skills. In order to assess the fidelity and acceptability of N/E, data sources will include: staff training logs, fidelity reach logs, staff field notes, notes from discussions at monthly team meetings, and notes from discussions with CAB members and at CAB meetings. Focus groups are an additional qualitative measure to assess fidelity and acceptability. These fidelity and acceptability data sources will assist the MSU based and FPCC-based research teams and the CAB to monitor

the enrollment of students and parents/legal guardians into the study, monitor the data submission, quality-check the data being reported, avoid potential study related bias or inconsistencies, and prepare interim reports when necessary.

D. Mandatory Reporting Safeguards: Procedures to prevent the violation of confidentiality will be limited by mandatory reporting requirements. Subjects will be informed in the consent document that the research team must report to authorities: (1) physical injury to any child caused by other than accidental means; and (2) information from a study participant that leads the research team to believe a person is in imminent danger of physical harm. The project personnel will inform parents or guardians if, in the judgment of the research team/project personnel, their child (under 18) is in imminent danger of trying to harm him/herself.

E. Research Team Safeguards: All research team/project personnel who interface in any way with intervention protocols, data collection, or data analysis are required to complete and be up-to-date with the extensive Collaborative Institutional Training Initiative (CITI) training and testing program and the NIH Good Clinical Practice Training. Weekly or monthly meetings or phone conferences will occur among the key personnel for ongoing training, monitoring of protocols, and problem solving. Questions concerning data collection will be processed during this time. The Project Director (Ms. FireMoon) will coordinate and oversee all activities at the data collection sites and will report all activities, concerns, and questions to the PI on an ongoing basis. Prior to the start of the intervention cycle, the entire team on the ground in the Fort Peck communities, including personnel to be hired, will be trained to identify events that would fall under mandatory reporting guidelines. These include physical injury to any child caused by other than accidental means, or information from a student participant that leads staff to believe a person is in imminent danger of physical harm.

F. Discomfort with Completing Intervention Data Collection Instruments or Disclosure Safeguards: During the course of participation in the research, a participant may have questions concerning the data collection tools. Either the Project Director (Ms. FireMoon) or the Outreach Coordinator (to-be-hired) will be available at each school data collection event to answer questions. Likewise, the mentoring program Director (Mrs. Growing Thunder) and her Community Mentorship Coordinator (to-be-hiredDo you want to add name?) will be available at each group mentoring meeting to answer questions. To prevent discomfort or embarrassment, the Project Director (Ms. FireMoon) is trained in counseling and has experience in therapeutic interaction. The PI has training and previous work experience in clinical social work and will be available to all participants via cell phone, email, or in person when she is at Fort Peck to address any concerns regarding the data collection instruments. The remaining staff will receive specialized training in sexual and reproductive health and will also be available to participants.

G. Dissatisfaction Safeguards: Participants will be encouraged to discuss with the PI or Fort Peck-based project personnel any possible dissatisfaction with the data collection tools or intervention activities.

3. Response Procedures for Adverse Events

A. Discomfort with Disclosure: All project personnel working in the reservation communities are under the supervision of the PI, who is highly trained in counseling. Any participant experiencing embarrassment or discomfort when completing data collection tools will be responded to in a compassionate and professional manner. If a participant experiences any other adverse reactions to the data collection tools or intervention activities/sessions, the participant will be referred to IHS Poplar Service Unit, HIS Wolf Point Service Unit, or the Fort Peck Tribes Health Promotion and Disease Prevention Program (HPDP) on the Fort Peck reservation, which all have trained psychotherapists available to tribal members. Participants will also be encouraged to contact the research team/project personnel in the event of a late adverse reaction and will receive specific written and verbal instructions during the project consent procedures about how to do so if the need arises.

B. Mandatory Reporting: Serious adversities shared by subjects that need to be reported by the research

team/project personnel include physical abuse and neglect or threat of physical harm to self or others. To anticipate these concerns, the research team/project personnel have established procedures and guidelines to respond to risk disclosures among participants.

Four types of situations require special procedures:

- **Suicide thoughts or attempts:** Two types of risks will be addressed in the project: (a) ideation or presentation of thoughts or interest in suicide, and (b) action, which includes both thoughts of suicide as well as the presence of a plan and means to accomplish a suicide act. As participants complete the data collection instruments, key personnel will review instruments and items for response values that indicate concern. Based on the response values, these key personnel will collectively review disclosed information and, if deemed necessary, conduct follow-up inquiry with the participant to further determine level of risk. If the participant is determined to present immediate risk, a referral will be made to one of the following, depending on which is most appropriate for the situation: IHS Poplar Service Unit, IHS Wolf Point Service Unit, or Fort Peck Tribes' Health Promotion and Disease Prevention Program, which offers mental health services to youth in schools. If the disclosure is the result of one of the written items on the data collection tools, Ms. FireMoon will contact the participant by telephone. If the disclosure occurs during an on-site session, the session leader will follow through with an in-depth interview to clarify the presence of suicidal risk and develop a plan of action. Session leaders and mentors will be trained and required to identify suicidal risks in both the domains of ideation and action. Session leaders will follow up in the same way and inform the PI. In the most extreme cases of risk, the PI then assumes follow-up responsibility for the plan of action.
- **Abuse:** Child abuse concerns may arise from any or a combination of the following sources: (a) the youth verbally indicates that abuse has occurred or is occurring; (b) the youth answers one or more data collection tool items suggesting the possibility of abuse; (c) the youth is observed being treated in an abusive manner; (d) the youth is observed with bodily injury (e.g., bruise, burns, black eyes) whose origin appears to differ from the explanation given of the injury. At any time during the completion of the data collection instruments, or during intervention sessions, if any of the above information leads key personnel or mentors to suspect abuse or neglect of children, documented steps will be followed to obtain additional information and personnel will contact the PI. Based on the information, the team will determine appropriate further inquiry and follow-up. Based on the information, the team will develop a safety plan that may include a participatory report to the Fort Peck Tribes/BIA Child Protective Services agency, and/or possible referral to the Fort Peck Tribes' Family Violence Resource Center based in Wolf Point.
- **Threat of danger to others:** The threat of danger to others includes disclosure of potential physical harm by a participant to others, including members of the participant's family or other individuals in the school or community. At any time during completion of data collection tools or during intervention sessions, if any information emerges suggesting the threat of harm to others, the team will review the information and determine next steps in accordance with the law, school policies, and the guidance of the CAB and project partners.
- **Addiction:** Addiction to substances is a condition characterized by compulsive substance intake, craving, and seeking, despite negative consequences associated with the substance(s) used. This project does not directly address substance abuse and addiction. However, the student survey asks about substance use, and some intervention sessions related to substance use occur outside of school settings. A situation may occur where a participant reveals information or exhibits characteristics that suggest addiction to substances. The key personnel and mentors will be trained to recognize signs and symptoms of addiction. Together with the PI they will determine the best response and plan for referral to Spotted Bull Addiction Services based in Poplar on the reservation.

C. SRH Health Risks and Needs: Due to the intervention and research subject matter of sexual and reproductive health, participants may reveal information during data collection or intervention sessions

that suggests either sexually transmitted infections, HIV, HCV, or suspected pregnancy. Key personnel and mentors will have received training on the services available through the local IHS Service Units to test and treat STIs, HIV, HCV, and/or to provide pregnancy testing and prenatal care. Participants who present these issues will be referred to the appropriate health practitioners for care, and project personnel will follow up with participants as needed to ensure action was taken to address health risks. The intervention program itself will encourage youth to access services for disease and pregnancy prevention.

4. Reporting Procedures for Adverse Events

The anticipated potential adversity inherent in the completion of the student survey is limited and will be addressed by the timely intervention of the key personnel and mentors, as appropriate—all with prior skills and/or training in risk assessment and mandatory reporting requirements. The occurrence of adverse events will be reported to the MSU and Fort Peck IRBs, the Data and Safety Monitoring Committee, and others as appropriate including the participating schools.

A. Reporting Procedure for Serious Unanticipated Adverse Events: In the event of an unanticipated serious adverse event, the PI and Project Director will ensure that these events are reported to the NIH Program Official within hours by phone, fax, and/or email and will submit a written report to the Program Official no more than two days later. Project personnel will also utilize the following reporting procedures:

- 1) When the research team/project personnel become aware of a serious adverse event, reporting requirements must be implemented in a timely manner.
- 2) The PI completes an Adverse Event Report and submits it to the MSU and Fort Peck IRB Chairs, to the project's Data and Safety Monitoring Committee, and to the project Community Advisory Board. The CAB will help identify culturally and socially appropriate ways of remedying adverse events.
- 3) The Chairs will convene expedited meetings of their respective IRBs. First the Fort Peck IRB and then the MSU IRB, with input from the PI and the Data and Safety Monitoring Committee, will review the study protocol and determine what further action to take based on the best interests of the participants and of the research.

5. Oversight

The boards that provide oversight to N/E are:

- Community Advisory Board
- The Fort Peck Institutional Review Board
- The Fort Peck Tribal Executive Board
- Montana State University Office of Research Compliance
- Montana State University Office of Sponsored Programs
- The Montana State University Institutional Review Board
- Data Safety and Monitoring Board

For the purposes of the Data Safety and Monitoring Plan, the Data Safety and Monitoring Board (DSMB) will be chaired by Dr. Jared Jobe, retired NIH program officer, Dr. David Huh, a researcher and statistician, Dr. William Lambert, a researcher, and Dr. Cynthia Pearson, a researcher. Meetings of the Committee will occur semi-annually by telephone or Zoom, and unless closed by the Chair, will be joined by the PI (Rink), the Project Director (Paula FireMoon), Ramey Growing Thunder, the Director of the Fort Peck Tribes Language and Culture Program, the study statistician (Mike Anastario), Dr. Julie Baldwin, the study co-Investigator, and the study's research program manager (Genevieve Cox). The DSMB will: a) review the research protocol and plans for data and safety monitoring; b) evaluate study progress, including data quality, participant recruitment rates, retention rates, outcome and adverse experience data, and risk versus benefit profile; and c) review the protocols to protect the confidentiality of the study data and the results of monitoring.

24

The study's community advisory board is updated quarterly on the study progress. The Fort Peck Tribal Executive Board, the Fort Peck IRB, the MSU IRB, and MSU's Office of Research Compliance and MSU's Office of Sponsored Programs are updated once a year on the study. The DSMB committee also will annually review the project's Data and Safety Monitoring Plan regarding: a) Reassessment of the risks and benefits to study participants; b) Participant recruitment, accrual, and retention; c) Data quality and confidentiality; d) Consideration of external scientific or therapeutic developments with impact on the safety of participants or the ethics of the study; e) Any adverse events.

The research team will update the general Data and Safety Monitoring Plan as well as the research protocols as needed. Adverse events will be reported to the Tribes, the participating schools, and the IRBs on an annual basis. Serious adverse events will be reported immediately to these entities as well as NIH and the DSMB. A written report will follow within 3 days of the event. The written report will be in the format required by the Tribes, schools, and the IRBs, and will contain information regarding the date of the event, description of the event, assessment of cause, whether the event indicates an increased risk for current or future subjects, and whether changes to the informed consent are necessary.